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John L. Beghin, M.D. John A. Shay, M.D

December 3, 1999

Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket Number 97N-484S

Dear Sirs:

The proposal referenced above would allow the FDA to regulate some types of allograft as medical devices. I oppose FDA regulation of allograft. My practice consists exclusively of lumbar spine surgery and over the past 15 years I have utilized many hundreds of structural allografts provided by various bone banks to the benefit of my patients. I have not experienced any significant problems with any of these products and I believe that regulation would impose unreasonable financial burden on the bone banks to satisfy FDA's premarket requirements. The requirement to sponsor clinical trials and submit lengthy regulatory documents would simply cause the bone banks to discontinue availability of these valuable products. Patients would be harmed. In my experience there is currently no problem requiring the heavy hand of regulation.

Sincerely,

John L. Beghin, M. D.

JLB:li

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